

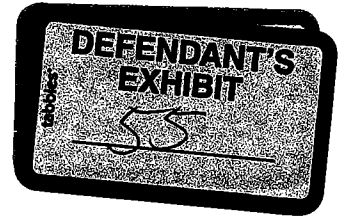
# **EXHIBIT 55**



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## Drugs

### Facts About Current Good Manufacturing Practices (cGMPs)



Current Good Manufacturing Practices (cGMPs) for human pharmaceuticals affect every American. Consumers expect that each batch of medicines they take will meet quality standards so that they will be safe and effective. Most people, however, are not aware of cGMPs, or how FDA assures that drug manufacturing processes meet these basic objectives. Recently, FDA has announced a number of regulatory actions taken against drug manufacturers based on the lack of cGMPs. This paper discusses some facts that may be helpful in understanding how cGMPs establish the foundation for drug product quality.

#### What are cGMPs?

cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA). cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards.

The cGMP requirements were established to be flexible in order to allow each manufacturer to decide individually how to best implement the necessary controls by using scientifically sound design, processing methods, and testing procedures. The flexibility in these regulations allows companies to use modern technologies and innovative approaches to achieve higher quality through continual improvement. Accordingly, the "c" in cGMP stands for "current," requiring companies to use technologies and systems that are up-to-date in order to comply with the regulations. Systems and equipment that may have been "top-of-the-line" to prevent contamination, mix-ups, and errors 10 or 20 years ago may be less than adequate by today's standards.

It is important to note that cGMPs are minimum requirements. Many pharmaceutical manufacturers are already implementing comprehensive, modern quality systems and risk management approaches that exceed these minimum standards.

#### Why are cGMPs so important?

A consumer usually cannot detect (through smell, touch, or sight) that a drug product is safe or if it will work. While cGMPs require testing, testing alone is not adequate to ensure quality. In most instances testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets), so that most of the batch can be used for patients rather than destroyed by testing. Therefore, it is important that drugs are manufactured under conditions and practices required by the cGMP regulations to assure that quality is built into the design and manufacturing process at every step. Facilities that are in good condition, equipment that is properly maintained and calibrated, employees who are qualified and fully trained, and processes that are reliable and reproducible, are a few examples of how cGMP requirements help to assure the safety and efficacy of drug products.

#### How does FDA determine if a company is complying with cGMP regulations?

FDA inspects pharmaceutical manufacturing facilities worldwide using scientifically and cGMP-trained individuals whose job it is to evaluate whether the company is following the cGMP regulations. FDA also relies upon reports of potentially defective drug products from the public and the industry. FDA will often use these reports to identify sites for which an inspection or investigation is needed. Most companies that are inspected are found to be fully compliant with the cGMP regulations.

#### If a manufacturer is not following cGMPs, are drug products safe for use?

If a company is not complying with cGMP regulations, any drug it makes is considered "adulterated" under the law. This kind of adulteration means that the drug was not manufactured under conditions that comply with cGMP. It does not mean that there is necessarily something wrong with the drug.

For consumers currently taking medicines from a company that was not following cGMPs, FDA usually advises these consumers not to interrupt their drug therapy, which could have serious implications for their health. Consumers should seek advice from their health care professionals before stopping or changing medications. Regulatory actions against companies with poor cGMPs are taken as a preventive measure because the manufacturing processes do not meet FDA's regulatory standards. By focusing on the procedures and processes used to make these drugs, FDA is working to ensure that drugs meet their quality standards and are safe and effective. The impact of cGMP violations depends on the nature of those violations and on the specific drugs involved. A drug manufactured in violation of cGMP may still meet its labeled specifications, and the risk that the drug is unsafe or ineffective could be minimal. Thus, FDA's advice will be specific to the circumstances, and health care professionals are best able to balance risks and benefits and make the right decision for their patients.

#### What can FDA do to protect the public when there are cGMP violations?

If the failure to meet cGMPs results in the distribution of a defective drug, the company may subsequently recall that product. This protects the public by removing these drugs from the market. While FDA cannot force a company to recall a drug, companies will usually recall voluntarily or at FDA's request. If a company refuses to recall a drug, FDA can warn the public and could seize the drugs that are on the market.

Even if the drugs are not defective, FDA can bring a seizure or injunction case in court to address cGMP violations. When FDA brings a seizure case, the agency asks the court for an order that allows federal officials to take possession of "adulterated" drugs and destroy them. This enables FDA to immediately prevent a company from distributing those drugs to consumers. When FDA brings an injunction case, FDA asks the court to order a company to stop violating cGMPs. Both seizure and injunction cases often lead to court orders that require companies to take many steps to correct cGMP violations, such as hiring outside experts, writing new procedures, and conducting extensive training of their employees. FDA can also bring criminal cases because of cGMP violations, seeking fines and jail time.

#### How would a new drug company learn about cGMPs and about FDA's expectations on complying with them?

FDA publishes regulations and guidance documents for industry in the *Federal Register*. This is how the federal government notifies the public of what we are doing and how we do it. FDA's website, [www.fda.gov](http://www.fda.gov)<sup>1</sup> also contains links to the cGMP regulations, guidance documents, and various resources to

help drug companies comply with the law. FDA also conducts extensive public outreach through presentations at national and international meetings and conferences, to discuss and explain the cGMP requirements, the latest policies, and the Agency's expectations. Guidance on the cGMP regulations can also be obtained through FDA's Small Business Representatives that are located throughout the country, through FDA District Offices, and from the Center for Drug Evaluation and Research, Office of Compliance, Division of Manufacturing and Product Quality.

#### FDA News Release

- U.S. Marshals Seize Drug Products Manufactured by Caraco Pharmaceutical Laboratories Ltd.<sup>2</sup>
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#### Links on this page:

1. <http://www.fda.gov/>
2. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2009/ucm169093.htm>